Message

From: McLaughlin, Jessica J [jessicamclaughlin@eastman.com]

Sent: 4/9/2019 6:22:57 PM

To: Garvie, Heather [Garvie.Heather@epa.gov]
CC: Roe, Lindsay [Roe.Lindsay@epa.gov]

Subject: RE: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Attachments: IIA 8.2.6-03 2001-1001846.pdf

Flag: Flag for follow up

Hello Heather,

Per our phone conversation, I was recently made aware of the fact that I have access to the attached study. I believe this study can be used to help satisfy Non-vascular aquatic plant toxicity study (guideline 850.4500). I will upload this study through the CDX portal as well, but I want to make sure you receive a copy.

Thank you, Jessica

From: Garvie, Heather < Garvie. Heather@epa.gov>

Sent: Monday, April 08, 2019 7:18 AM

To: McLaughlin, Jessica J < jessicamclaughlin@eastman.com>

Cc: Roe, Lindsay < Roe.Lindsay@epa.gov>

Subject: RE: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Hi Jessica:

We will let you know once it gets through the system and up to us. But rest assured that you met the cut off date for the response as you sent it directly to me. We are working on the rest of the information you sent. As soon as I have our responses compiled we will be in touch.

Thanks, Heather

From: McLaughlin, Jessica J < jessicamclaughlin@eastman.com >

Sent: Friday, April 05, 2019 4:32 PM

To: Garvie, Heather < Garvie. Heather@epa.gov>

Subject: RE: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Hi Heather,

I have submitted our waiver request through CDX. To be honest, I'm not confident I did it correctly, but it went through and CDX says "In Transmission". Can you let me know when/if you receive it properly? Otherwise, I will send it via FedEx on Monday if I need to do so. Are there any updates on our 10 day deficiency letter? I'm hopeful EFED will find our response to the letter acceptable. I look forward to hearing from you soon.

Thank you, Jessica

From: Garvie, Heather < Garvie. Heather@epa.gov>

Sent: Wednesday, April 03, 2019 8:28 AM

To: McLaughlin, Jessica J < jessicamclaughlin@eastman.com >

Cc: Roe, Lindsay <<u>Roe, Lindsay@epa.gov</u>>; Giles-Parker, Cynthia <<u>Giles-Parker, Cynthia@epa.gov</u>> **Subject:** RE: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Jessica:

Thank you again for this submission. You have now responded to all of the deficiencies as noted in the 10 day letter. We will be in touch once we have completed our review of your responses. In the meantime please submit this waiver request to the portal so that it can receive a MRID. In your cover letter please state that this is in response to the Agency's 10-day deficiency letter.

Thank you, Heather

From: Garvie, Heather

Sent: Wednesday, April 03, 2019 7:29 AM

To: McLaughlin, Jessica J < iessicamclaughlin@eastman.com >

Cc: Roe, Lindsay <<u>Roe, Lindsay@epa.gov</u>>; Giles-Parker, Cynthia <<u>Giles-Parker, Cynthia@epa.gov</u>> **Subject:** RE: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Thank you Jessica.

From: McLaughlin, Jessica J < jessicamclaughlin@eastman.com >

Sent: Tuesday, April 02, 2019 4:10 PM

To: Garvie, Heather < Garvie. Heather@epa.gov>

Cc: Roe, Lindsay <<u>Roe, Lindsay@epa.gov</u>>; Giles-Parker, Cynthia <<u>Giles-Parker, Cynthia@epa.gov</u>> Subject: RE: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Hello Heather,

I have attached our waiver request for guideline 835.4200 – anaerobic soil metabolism study. I look forward to hearing from you on the remaining open items.

Thank you, Jessica

From: Garvie, Heather < Garvie. Heather@epa.gov>

Sent: Monday, April 01, 2019 11:59 AM

To: McLaughlin, Jessica J < jessicamclaughlin@eastman.com >

Cc: Roe, Lindsay < Roe, Lindsay@epa.gov >; Giles-Parker, Cynthia < Giles-Parker, Cynthia@epa.gov > Subject: RE: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Hi Jessica:

We are still looking over your response to the 2^{nd} 10-day deficiency letter. However, we did want to get back to you regarding guideline 835.4200 (anaerobic soil metabolism study). You stated that you could submit a waiver write up for this guideline in your March 27^{th} response. You are welcome to submit this waiver for review as long as it is received by 4/10/19. The three studies that you cited (MRIDs 47769405; 47769406; and 47769407) do not reflect an anaerobic soil metabolism study guideline.

We want to make it clear that we are still looking over your other responses and have not yet determined if all of your responses satisfy the deficiencies. Therefore submitting the waiver for 835.4200 is not a guarantee that

the Agency will find your other responses adequate. Once we have completed reviewing all of your other responses we will be in touch.

If you chose to submit the waiver for 835.4200 it should be emailed directly to me.

Thank you, Heather

From: McLaughlin, Jessica J < jessicamclaughlin@eastman.com>

Sent: Wednesday, March 27, 2019 4:22 PM **To:** Garvie, Heather < Garvie. Heather@epa.gov>

Subject: RE: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Hello Heather,

The following documents are attached for your review:

- An updated data matrix. The changes to the data matrix were outlined in my response letter I emailed you earlier.
- Study titled "Masse, A.M., (2018). Manipulator™ Validation of the Analytical Method for the Determination of the Active Substance Chlormequat Chloride in Aqueous Solutions. Smithers Viscient Study No. 14105.6124. 68 pp." This study was assigned MIRD 50747517
- The Product Specification Form (PSF) that shows the formulation of Manipulator in Canada. This is to prove Manipulator and Adjust are the same end use products.

I look forward to your feedback.

Thank you, Jessica

From: Garvie, Heather < Garvie. Heather@epa.gov>

Sent: Tuesday, March 26, 2019 1:32 PM

To: McLaughlin, Jessica J < jessicamclaughlin@eastman.com >

Subject: [I] 10 -day deficiency letter for Section 3 - first food use - please confirm receipt

Hi Jessica:

We received the science screens from HED and EFED. HED did not identify any deficiencies during their initial screen; however EFED did. Please see the attached deficiency letter and confirm receipt via email.

Thank you, Heather

Heather A. Garvie
Senior Regulatory Specialist
Fungicide Branch
Registration Division
Office of Chemical Safety and Pollution Prevention (7504P)
U.S.EPA
1200 Pennsylvania Ave. NW
Washington, DC 20460
phone: 703-308-0034
www.epa.gov

